Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria® for appropriate imaging work-up of palpable breast masses.

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Women's Imaging-Breast Work Group. Appropriate imaging work-up of palpable breast masses. Reston (VA): American College of Radiology (ACR); 2003. 4 p. (ACR appropriateness criteria). [28 references]

GUIDELINE STATUS

This is the current release of the guideline.

It is a revision of a previously issued version: Appropriate imaging work-up of palpable breast masses. American College of Radiology, ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl).

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Palpable breast mass
Breast cancer

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Obstetrics and Gynecology
Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of radiologic exam procedures for imaging and treatment decisions in the work-up of palpable breast mass

TARGET POPULATION

Women with palpable breast masses

INTERVENTIONS AND PRACTICES CONSIDERED

1. Diagnostic mammography
2. Supplemental mammographic views
3. Ultrasound exam

MAJOR OUTCOMES CONSIDERED

Diagnostic utility (i.e., sensitivity, specificity) of radiologic exam procedures in the evaluation of a palpable breast mass

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine's MEDLINE database. The developer identified and collected the major applicable articles.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the most to the least appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Task Force on Appropriateness Criteria and the Chair of the ACR Board of Chancellors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Work-up of Palpable Breast Mass

Variant 1: Palpable Breast Mass in Woman 30 years of age or older

Radiologic Exam Procedure	Appropriateness Rating	Comments
Diagnostic Mammography (Craniocaudal, mediolateral oblique view of each breast, marker on mass)	9	
Supplemental Mammographic Views	8	
Ultrasound Exam	8	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 2: Palpable Breast Mass in Woman less than 30 years of age

Radiologic Exam Procedure	Appropriateness Rating	Comments
Ultrasound Exam	9	
Diagnostic Mammography (if ultrasound shows the following):		
Ultrasound shows benign or probably benign findings	2	
Ultrasound is equivocal or negative for findings	8	Diagnostic mammogram tailored to clinical situation
Ultrasound is suspicious or highly suggestive of malignancy	9	Bilateral diagnostic examination

Radiologic Exam Procedure	Appropriateness Rating	Comments
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Breast cancer is the most common female malignancy and the second leading cause of cancer deaths in the United States. This year an estimated 182,000 new cases of female breast cancer will be diagnosed, and a breast mass will be the most frequent surgical indication. A palpable breast mass may become evident during breast self-examination (BSE), clinical breast examination (CBE), or retrospectively following screening mammography.

Determining by physical examination if a mass is present can be difficult, as all breasts have variable combinations of glandular tissue, fibrosis, and fat. True masses are generally asymmetrical in relation to the other breast, distinct from the surrounding tissues, and three-dimensional. A typical cancer may be firm, have indistinct borders, and have attachments to the skin or deep fascia with dimpling or nipple retraction. Benign lesions typically have discrete, well-defined margins and are mobile. Cysts can be difficult to distinguish by palpation from solid masses. In one study, only 58% of 66 palpable cysts were correctly identified by physical examination. Significant disagreement among experienced examiners may occur. In another study, four surgeons performed physical examination independently and agreed on the need for biopsy of only 73% of 15 masses subsequently proven malignant.

Because many breast masses may not exhibit distinctive physical findings, an imaging evaluation is necessary in almost all cases to characterize the palpable lesion and screen the remainder of each breast for additional lesions. Unfortunately not all palpable breast masses will be visualized with conventional imaging techniques. In the Breast Cancer Detection Demonstration Project (BCDDP) begun in the 1970s, 9% of the cancers were found by CBE alone. With improvement in imaging methods since the BCDDP, this percentage should be considerably less. Nevertheless a negative imaging evaluation should never overrule a strongly suspicious finding on physical examination or vice versa.

Several imaging techniques are commonly used in the evaluation of palpable breast masses. Screening mammography is most useful for early detection of nonpalpable breast lesions. The examination is performed on women thought to be asymptomatic and usually consists of craniocaudal and mediolateral oblique views of each breast. A mass found with screening mammography may become perceptible by palpation after its location has been identified radiographically. Following detection of a clinical or mammographic mass, diagnostic mammography may be performed. A small metal marker is placed on the skin over the mass to identify its location. Supplemental mammographic views may be needed to clarify the features, location, or reality of a mammographic lesion. These views have been discussed extensively and include spot compression, spot compression/magnification, magnification, exaggerated craniocaudal to the medial or lateral side, tangential, change of angle, cleavage, cleopatra, and 90-degree

lateral view. Any creative nonstandard view may be used to image a lesion or move it closer to the film. These supplemental views improve visualization of palpable and nonpalpable masses and are predictive of whether they are benign or malignant.

Sonography was initially used only to differentiate cystic from solid lesions. Many palpable masses not visualized mammographically are cysts and can be diagnosed sonographically. With the development of 7.5-10 MHz linear array transducers with excellent near-field resolution, the role of sonography has expanded to include characterization of the shape, margins, and internal matrix of masses and guidance for needle localization, aspiration, and biopsy. Sonography is also highly accurate in identifying palpable malignant breast masses, although no one exam alone should be used to exclude malignancy.

Fine-needle aspiration/biopsy (FNA) is used to remove fluid from a cyst and cellular material from a solid mass. Some physicians suggest FNA as the first means of evaluation following physical examination, and patients with a palpable mass referred for imaging evaluation may have already undergone FNA.

Stereotactic (x-ray) or ultrasound guidance may be used for FNA and/or core biopsy if the mass is vaguely palpable, small, deep, mobile, or multiple, or attempts using palpation to biopsy the mass have been unsuccessful.

The use of multiple modalities in the diagnosis of palpable masses has been advocated as a measure to increase the true positive rate. In one study comparing physical examinations, mammography, and ultrasound, the authors concluded that for palpable masses, physical examination, and ultrasound formed the optimal preoperative test combination. Mammography was also necessary to detect occult cancer in the contralateral or ipsilateral breast. Diagnostic breast ultrasound can improve the specificity of clinically detected abnormalities. The most common use today is for cyst-solid differentiation and guidance for biopsy procedures. However, using strict criteria for benign and malignant features for solid masses seen on ultrasound, a high negative predictive value (99.5%) is possible to achieve. When both mammography and sonography are negative or benign in the evaluation of a palpable breast mass, the negative predictive value is also very high (99.8%). Together, these imaging modalities can be reassuring when the physical examination is not highly suspicious and follow-up is planned. However, a highly suspicious physical examination should prompt biopsy regardless of the imaging findings.

Other imaging techniques are still investigational. With the introduction of contrast agents and specific coils dedicated to breast imaging, magnetic resonance imaging (MRI) has emerged as a promising modality for detection, diagnosis, and staging of breast cancer. The sensitivity of MRI is high, but the specificity of the exam is problematic with many false positives resulting. There is an ongoing multicenter trial, which will hopefully clarify the role MRI plays in breast cancer diagnosis. There are many novel MRI sequences that are aimed at diminishing the false positive exams while maintaining a high sensitivity. Exciting new prospects for breast cancer detection using molecular imaging are now being actively investigated. A study comparing positron emission tomography (PET) using an isotope of glucose and single-photon-emission computed tomography (SPECT) indicate that both techniques are comparable in diagnosing breast

cancer, with a sensitivity of 79% for PET and 76% for MIBI SPECT. More work must be done to establish criteria for the use of molecular imaging for breast cancer diagnosis.

Because of the theoretical increased radiation risk and the low incidence of breast cancer (less than 1%) in women younger than 30 years of age, the imaging evaluation for patients over 30 years of age differs from that performed for younger patients, according to most investigators. As with all age-related guidelines, pertinent clinical factors such as family history should be used to determine appropriate patient care.

In determining the utility of mammography in women younger than 30 years of age, most researchers have retrospectively either studied patients referred for mammography or reviewed the mammographic findings of patients in whom cancer was found. In the first group of studies, as one would expect, there was a predominance of benign masses and nonspecific benign findings, although a few carcinomas were found. Most of the benign lesions were not visualized mammographically, and sonography was suggested as the initial imaging modality. Mammography was recommended as a preoperative assessment only in cases where cancer was strongly suspected clinically. As with women 30 years of age and older, most investigators agree that if physical examination is highly suspicious and mammography is negative, tissue sampling with FNA, core biopsy, or surgical biopsy is warranted. In symptomatic young women subsequently proven to have breast cancer, mammography was abnormal preoperatively in 86-90%, of them, suggesting it is of substantial value in the diagnosis of malignancy.

For this exercise, two variants will be considered: patients younger than 30 years of age with a palpable breast mass and those 30 years of age and older.

Anticipated Exceptions

None

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate selection of radiologic exam procedures for the evaluation of a palpable breast mass

POTENTIAL HARMS

False-positive and false-negative results of imaging studies for palpable breast masses

CONTRAINDICATIONS

CONTRAINDICATIONS

Asymptomatic women younger than 30 years of age

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Task Force on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other coexistent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the United States Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 Sep (revised 2003)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

ACR Appropriateness Task Force, Expert Panel on Women's Imaging - Breast Work Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

Print copies: Available from ACR, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 25, 1999. The information was verified by the guideline developer on September 9, 1999. The NGC summary was updated on November 12, 2004. The information was verified by the guideline developer on December 21, 2004.

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